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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,731	02/27/2004	Jason R. Fink	58210US004	6098

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/788,731	FINK ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *7,8,23,24 and 35-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-22 and 25-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/13/04; 10/20/04; 11/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Election/Restrictions:

1a. Applicants' election without traverse of Group I, (claims 1-6, 9-22, 25-34), filed on 25 August 2006 is acknowledged.

The restriction requirement is still deemed proper and is therefore made FINAL.

Status of Claims:

1b. Claims 1-55 are pending, of which claims 1-6, 9-22, 25-34 are drawn to elected invention and thus will be searched and examined.

Claims 7-8, 23-24 and 35-55 are withdrawn from consideration by the Examiner as they are drawn to non-elected invention.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 13 August 2004, 20 October 2004 and 28 November 2005 have been received and comply with the provisions of 37 CFR §1.97 and §1.98. The references have been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 U.S.C. § 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6, 9-22 and 25-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 1, 9 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Claim 1 is drawn to a method of identifying a compound that modifies a TLR-mediated cellular activity and claim 9 is drawn to a method of identifying a target compound having a TLR modulation profile, however the claims fail to recite positive steps of how to achieve the desired result. Claim 1 recites "...providing an assay...", however, it is unclear which assay to use, what is the starting material for the claimed method, what to test for and what result to expect. Likewise, it is unclear how to identify a "TLR modulation profile", recited in claim 9. The specification describes a "TLR modulation profile" on pages 17-20, of the specification, where it indicates that a "TLR modulation profile" includes representative effects characteristic of modulating at least one TLR-mediated cellular activity. However, one of skill in the art would not be able to practice the claimed method, because there is no disclosure of what is the starting material, what type of assay to perform and what results should be expected to achieve. Claim 25 recites a method of identifying a first immune system cell population and a second immune system cell population, however, neither the claim nor the specification describes how to identify or select said first and/or second immune system cell populations, what characteristics to look for in each cell population and what differences or similarities to expect. Appropriate correction is required.

Claims 2-6, 24, 26-34 are vague and indefinite so far as they depend from claim 1 or claim 14 for the limitations set forth directly above.

Priority:

4. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is entitled to the effective filing date of 27 February 2003, which is the filing date of the Provisional Parent Application Number 60/450,484.

Claim rejections-35 USC § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

5a. Claims 1-6 and 25-34 are rejected under 35 U.S.C § 102(b) as being anticipated by Hemmi et al (January 2002).

It is understood that instant claims 1-6 are drawn to a method of identifying a compound that selectively modulates at least one TLR-mediated activity, while claims 25-34 are directed to a method of modulating immune cells. No meaningful interpretation can be obtained for claims 9-24, because the disclosure does not describe or teach how to identify a "TLR modulation profile".

Hemmi et al disclose a method of screening for compounds that activate TLRs by incubating a test compound with peritoneal macrophages from wild type or TLR deficient mice and measuring cytokine production. The researchers found that macrophages from TLR2, TLR4, TLR6 and TLR9 deficient mice produced normal amounts of TNF-α in response to test compound (imidazoquinolines), (see page 197,

column 2 and page 198, column 1). The researchers also disclose that TLR7 deficient macrophages produced normal amounts of cytokines in response to immunostimulatory CpG DNA, (fig 2e). However, the researchers discover that peritoneal macrophages from wild type mice produced normal TNF-α, IL-6 and IL-12 in response to imiuquimod and R-848, whereas TLR7 deficient macrophages produced no detectable amount of these cytokines, (page 199, column 1 and fig 3a). Regarding claim 25, Hemmi et al use peritoneal macrophages from wild type and peritoneal macrophages from TLR deficient mice.

The Hemmi et al reference discloses a method of screening for compounds that modulate a TLR-mediated cellular activity (e.g production of cytokines), provides a means of testing this effect (wild type vs TLR deficient macrophages), and shows that some of the TLR receptors do not confer responsiveness to the test compounds, while others do, (see methods and material on pages 199-200).

Therefore, the Hemmi et al reference anticipates the instant claims 1-6 in the absence of any evidence to the contrary.

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5b. Claims 1-6 are rejected under 35 U.S.C § 102(a) as being anticipated by Jurk et al (June 2002).

Jurk al disclose a method of screening or compounds for their potential to activate HEK293 cells that were transiently transfected with TLR cDNAs and a NF-kB luciferase reporter plasmid, (see columns 2-3). The authors found that R-848 induced NF-kB activation in HEK293 cells transfected with human TLR7 and TLR8. Thus, the

authors conclude that both human TLR7 and TLR8 mediate recognition of the same antiviral compound R-848. The Jurk et al reference discloses a method of screening for compounds that modulate a TLR-mediated cellular activity (e.g NF-kB activation), provides a means of testing this effect and shows that both TLR7 a nd TLR8 confer responsiveness to R-848.

Therefore, the Jurk et al reference anticipates the instant claims 1-6 in the absence of any evidence to the contrary.

5c. Claims 1-6 are rejected under 35 U.S.C § 102(a) as being anticipated by Gibson et al (August 2002).

Gibson al disclose that TLR7 agonists stimulate human plasmacytoid dendritic cells (pDC) to produce a number of cytokines including TNF-α, IP-10, interferon-α and interferon-ω, (see page 78, figure 4). The authors show that certain compounds activate NF-kB through TLR7 but not through TLR9, (see table 2). Therefore, the Gibson et al reference anticipates the instant claims 1-6 in the absence of any evidence to the contrary.

Conclusion:

6. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
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Art Unit 1647
16 September 2006

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